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Serels S[1], Nosseir S[2], Lind L[2], Winkler H[2]
1. *Bladder Control Center Of Norwalk,* ***2.*** *North shore LIJ, Division of urogynecology*

PROSPECTIVE MULTI-CENTER STUDY LOOKING AT THE SAFETY AND EFFICACY OF THE SOLYX™ SIS SYSTEM

Hypothesis / aims of study

The midurethral polypropylene sling is considered the standard surgical treatment for Stress Urinary Incontinence(SUI) with the retropubic and transobturator slings typically used. However, as reported in the literature, significant rates of complications are seen with both methods (i.e. bowel and bladder perforation, leg and groin pain). The Solyx™ Single-Incision Sling (SIS) System was developed to potentially reduce the post-op complication rate seen with other slings, yet maintain the successful patient outcomes. The objective of this study was to prospectively assess the short-term safety and efficacy of the Solyx™ SIS Sling System.

Study design, materials and methods

20 patients from 2 centers scheduled to receive surgery with the Solyx™ SIS System were enrolled. All patients were diagnosed with SUI, had urethral hypermobility with a Q-tip test > 30 degrees. Patients were evaluated pre-operatively, at 2 and 6 weeks, and at 3 months. The primary safety endpoint was an assessment of device-related serious adverse events peri-operatively and at 3 months; tolerability was assessed via patient questionnaires (UDI-6, I-QOL). Secondary endpoint was patient questionnaires and a cough stress test at 3 months.

Results

20 patients were enrolled and at least 6 week follow up data was availabl for 15 patients. Mean age was 63 years, (range 39-82) and mean parity was 2.7 (range 1-5) . All subjects received the Solyx™ SIS System, a minimally invasive single- incision sling, with mesh placed under the urethra and anchored in the obturator internus muscles. 11 patients (61.0%) underwent concomitant procedures. All patients were discharged in < 23 hours . Fourteen patients have already been evaluated 3 months post-operatively, and 13 had a negative cough stress test. Preoperative mean UDi-6 and I-QOL were 48.8 and 73.2 respectively. At 6 weeks (n=15) mean UDI-6 and I-QOL were 15.4 and 99.7 and at 3 mos (n=14) 10.7 and 100.3 respectively. Four (22%) patients had a component of urgency preoperatively which required medication while only 2 required medication postoperatively. At 3 months all patients were satisfied with the procedure, and all but one said that they would do it again. There were no serious adverse events including no bladder, bowel, vessel or nerve perforations and no erosions or extrusions. No pain was reported that was attributed to the implant.

Interpretation of results

This short-term, prospective analysis provides supporting data that the Solyx™ SIS System has an acceptable safety profile, with no device-related adverse events, and a high patient tolerability.

Concluding message

Early efficacy data provides preliminary evidence for patient outcomes yet long term data is needed.

Specify source of funding or grant	**restricted grant form Boston Scientific Corporation**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Norwalk Hospital and Long Island Jewish Hospital**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**